SmartPA Criteria Proposal

Drug/Drug Class:	Ampyra Clinical Edit
First Implementation Date:	June 30, 2011
Proposed Date:	July 18, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Ampyra® (dalfampridine)

Why Issue Selected: Multiple Sclerosis (MS) is an inflammatory demyelinating disease of the central nervous system that involves a disease course marked by periods of relapse, increasing functional impairment over time, and decreased quality of life. Almost one million people are living with MS in the United States, with most people diagnosed between the ages of 20 and 50 years. The average person in the United States has about a one in 750 chance of developing MS, and it is at least 2–3 times more common in women than in men. Several agents are approved for use in MS to reduce the frequency of relapses and slow disease progression. Ampyra®, FDA approved in 2010, is a broad spectrum potassium channel blocker indicated as a treatment to improve walking in adults with MS, demonstrated by an increase in walking speed. Ampyra is believed to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels. It does come with several warnings, however, including a potential to cause seizures. Due to the possible adverse events and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Ampyra.

Program-Specific Information:

Date Range FFS 4-1-2022 to 3-31-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
AMPYRA ER 10MG TABLET	269	$12,215.25	$45.41

Type of Criteria:
- ☒ **Increased risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **Clinical Edit**

Data Sources:
- ☒ **Only Administrative Databases**
- ☐ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Ampyra® (dalfampridine)
- Age range: All appropriate MO HealthNet participants

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Approval Criteria

- Documented diagnosis of Multiple Sclerosis (MS) **AND**
- Claim does not exceed 2 tablets per day

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented diagnosis of seizures
- Documented diagnosis of moderate to severe renal insufficiency

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- AMPYRA® (dalfampridine) [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; June 2022.
- American Academy of Neurology. Practice Guideline Systematic Review Summary: Disease-Modifying Therapies for Adults with Multiple Sclerosis. Practice Guideline Systematic Review Summary: Disease-modifying Therapies for Adults with Multiple Sclerosis (aan.com). April 2018.
- Levin, Michael C. Multiple Sclerosis (MS). Multiple Sclerosis (MS) - Neurologic Disorders - Merck Manuals Professional Edition. March 2021.
- IPD Analytics. CNS: Multiple Sclerosis. Accessed May 5, 2023.

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